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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,517	10/16/2003	Edgar Hommann	33628/US	5234

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EXAMINER

MEHTA, BHISMA

ART UNIT PAPER NUMBER

3767

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,517

Applicant(s)

HOMMANN ET AL.

Examiner

Bhisma Mehta

Art Unit

3767

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/26/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Part of the information disclosure statement filed January 26 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The reference, which has been crossed out by the examiner, has not been considered because there is no concise explanation of relevance for this reference.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 13, 56, 20', 26. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Art Unit: 3767

2. The drawings are objected to because the reference characters in Figure 2d are unclear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it contains legal phraseology (i.e. means. Correction is required. See MPEP § 608.01(b).

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose an oblique surface being

Art Unit: 3767

provided on the dispensing means and a guiding means being provided to guide when the injection needle is placed onto or removed from the product container. The specification also fails to disclose a setting element projecting through an opening in the casing of the injection device and the dimensions of the opening limiting movement of the setting element in accordance with a predetermined dose amount.

5. The disclosure is objected to because of the following informalities:

a. The sentence beginning "In one embodiment..." in line 17 of page 7 appears to have a word missing. The sentence beginning "In some embodiments..." in line 28 of page 14 appears to have a grammatical error.

b. There are numerous instances where a reference character has been used to designate two separate things. For example, reference character 2 has been used for an injection needle in line 23 of page 11 and for a split nut in line 21 of page 13. Reference character 4 has been used for a piston in line 24 of page 11 and for a split nut sleeve in line 21 of page 13. Reference character 1 has been used for a product container in line 22 of page 11, for a threaded drive rod assembly in line 23 of page 13, and for a sleeve in line 28 of page 13.

Reference character 3 has been used for a casing in line 23 of page 11 and for a threaded drive rod assembly in line 23 of page 13. Reference character 17 has been used for an activating member in line 16 of page 13 and for a scale drum in line 27 of page 15. Reference character 19 has been used for a threaded drive rod assembly in line 23 of page 13 and for a grating in line 29 of page 15.

Reference character 21 has been used for a side lever in line 17 of page 13 and

Art Unit: 3767

for a sleeve-shaped element in line 4 of page 16. Reference character 23 has been used for a housing in line 29 of page 13 and for a lever in line 30 of page 16. Reference character 24 has been used for a housing in line 29 of page 13 and for an opening in line 1 of page 17.

Appropriate correction is required.

Claim Objections

6. Claims 6-10, 12, 13, and 18 are objected to because of the following informalities: Claim 6 recites the limitations "said setting element" in line 5, "the setting element" in lines 6-7 and "said predetermined dosage amount". Claim 7 recites the limitation "the predetermined dosage amount " in line 1. Claim 8 recites the limitation "the dosing means " in line 3. Claim 9 recites the limitation "the setting element " in line 2. Claim 10 recites the limitations "said fluid product " in line 2 and "said product container" in line 3. Claim 12 recites the limitation "the injection needle " in line 2. Claim 13 recites the limitation "the injection needle " in line 2. Claim 18 recites the limitation "the setting element " in line 3. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3767

8. Claims 4, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, it is unclear what the word "they" is referring to. In claims 12 and 13, it is unclear what the guiding means are intended to guide.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-3, 5, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronvig (U.S. Patent No. 5,433,352). Ronvig discloses an injection device having a casing (2), dispensing means (20), and operating means (22). The operating means are provided laterally on a circumferential surface of the casing and are pivotable in a radial direction about a fulcrum (26, 27) which is arranged laterally on the injection device. The operating mean also comprises a protrusion which is co-operable with the dispensing means via a surface oblique relative to a longitudinal axis of the casing. The protrusion of the operating means can be considered to be any

Art Unit: 3767

portion of the operating means which has a surface which is oblique relative to the longitudinal axis of the casing. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The fulcrum is provided on the circumferential surface in a generally central area of the injection device. In lines 34-40 of column 4, Ronvig discloses an indicator in the form of a toothed bar (20) and a latch (25) where the latch pushes the toothed bar a predetermined distance towards the front end of the injection device, thus indicating a product amount in the product container. The indicator is operated by pivoting the operating means.

11. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al (U.S. Patent No. 5,507,70). Haber et al disclose an injection device having a casing (4), dispensing means (12), and operating means (18). The operating means are provided laterally on a circumferential surface of the casing and are pivotable in a radial direction about a fulcrum (22) which is arranged laterally on the injection device. The operating mean also comprises a protrusion which is co-operable with the dispensing means via a surface oblique relative to a longitudinal axis of the casing. The protrusion of the operating means can be considered to be any portion of the operating means which has a surface which is oblique relative to the longitudinal axis of the casing. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. Haber et al teach that the protrusion is connected to the dispensing means by a T-connection (48) which allows the dispensing means to guide or slide relative to the operating means. Haber et al disclose an indicator in the form of a barrel

Art Unit: 3767

(4) for indicating a product amount in the product container and the indicator is operated by pivoting the operating means.

12. Claims 1-3, 5-9, and 14-20 are rejected under 35 U.S.C. 102b) as being anticipated by Cosmai (U.S. Patent No, 4,850,967). Cosmai discloses an injection device having a casing (24), dispensing means (29), and operating means (13). The operating means are provided laterally on a circumferential surface of the casing and are pivotable in a radial direction about a fulcrum (45) which is arranged laterally on the injection device. The operating mean also comprises a protrusion which is co-operable with the dispensing means via a surface oblique relative to a longitudinal axis of the casing. The protrusion of the operating means can be considered to be any portion of the operating means which has a surface which is oblique relative to the longitudinal axis of the casing. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The fulcrum is provided on the circumferential surface in a generally central area of the injection device. In lines 17-43 of column 7, Cosmai discloses an indicator (47, 50) in the form of a slider and graduation markings indicating a product amount in the product container. Pivoting the operating means which causes the dispensing means to be advanced, thus moving the slider, operates the indicator. The injection device also includes a dosing means with a releasing element (56) which projects through an opening in the casing. The releasing element is moved from a first stopper on the opening which is where the element contacts a portion of the opening to a second stopper on the opening which is where the element contacts another portion of the opening when the element is in its moved position. The dimensions of the

Art Unit: 3767

opening limit the movement of the releasing element in accordance with a dose amount. The indicator comprises a scale (i.e. the markings) and count down by a dosage unit when the dispensing means are operated. As to claim 19, the sleeve (16) is considered to be capable of surrounding an injection needle and being shiftable.

13. Claims 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillespie, III (U.S. Patent No. 6,387,078). In Figures 1 and 6, Gillespie, III discloses an injection device having a casing (115), a holder (410), an injection needle (540), a needle protector in the form of a sleeve (105), and a spring (505) which holds the sleeve in an advanced position. As to claim 13, the hole of the needle hub (530) is considered to be the guiding means which guide the injection needle.

14. Claims 10, 11, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hommann et al (U.S. Patent Application Publication No. 2003/0144632)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In Figures 2 and 3, Hommann et al disclose an injection device having a casing (12), a holder (14), an injection needle (16), a needle protector in the form of a sleeve (20), and a spring (34) which holds the sleeve in an advanced position. As to claim 13,

Art Unit: 3767

the front end of the holder is considered to be the guiding means which guide the injection needle.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronvig in view of Burroughs et al (U.S. Patent No. 6,001,089). Ronvig discloses the injection device substantially as claimed. As to claim 12, the hole (10) and the membrane at the front end of the product container are considered to be the guiding means which guide the injection needle. However, Ronvig is silent on the injection device having an indicator (150) which includes a scale up to a total number of dosage amounts contained in the product container and counts down by a dosage unit when the dispensing means are operated. In lines 19-61 of column 8, Burroughs et al disclose a injection device having an indicator comprising a scale to indicate the total number of dosage amounts contained in the product container and counts down by one unit when the dispensing means are operated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the injection device of Ronvig with the components of the indicator of Burroughs et al as Ronvig discloses

Art Unit: 3767

injecting a predetermined amount of fluid into a patient and Burroughs et al teach an indicator which would allow one to know when a dosage unit has been injected.

17. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ronvig in view of Hommann et al. Ronvig discloses the injection device substantially as claimed. However, Ronvig is silent on the injection device having a shiftable sleeve arranged such that, in one position, the sleeve surround an injection needle. In Figures 2 and 3, Hommann et al disclose an injection device having a casing (12), a holder (14), an injection needle (16), and a needle protector in the form of a sleeve (20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the injection device of Ronvig with a shiftable sleeve as taught by Hommann et al as Hommann et al teach that it is well known to used a shiftable sleeve as a means for maintaining the injection needle in a protected position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

